OCT 3 0 2000

K002325

510(k) Summary

Submitted By: BioPro
17 17th Street
Port Huron, MI 48060

Contact: Michael G. Tanner
(810) 987-7777 Fax: (810) 982-7794

Device Information:

proprietary name: Wujin #3 Tibial Nail
common name: Rod, Fixation, Intramedullary and Accessories
classification name: Rod, Fixation, Intramedullary and Accessories

Wujin #3 Tibial Nail:

The Wujin #3 Tibial Nail will be available in two material options; it can be manufactured from either 316 LS (ASTM F138) or Titanium 6-4 (ASTM F1472). The Wujin #3 Tibial Nail (manufactured from 316LS) will be available in 21 sizes (item numbers: 15695, 15753-15772) and is to be used in conjunction with four Tibial Locking Screws and one Tibial Nail Plug (each manufactured from 316LS). The Wujin #3 Tibial Nail (manufactured from Titanium 6-4) will be available in 21 sizes (item numbers: 16446-16466) and is to be used in conjunction with four Femoral Locking Screws and one Tibial Nail Plug (each manufactured from Titanium 6-4).

Substantial Equivalence:

The Wujin #3 Tibial Nail is substantially equivalent to the Alta® Advance Tibial/Humeral Rod. See Appendix B for more information on the Alta® Advance Tibial/Humeral Rod. Both styles possess four holes and are to be used in conjunction with four Femoral Screws and a Plug. The Wujin #3 Tibial Nail is available in either Titanium or LS316, while the Alta® Advance Tibial/Humeral Rod is only available in Titanium. Unlike the Wujin #3 Tibial Nail (which is designed for Tibial applications), the Alta® Advance Tibial/Humeral Rod is designed for both Tibial and Humeral applications.

Although there are minor differences between the Wujin #3 Tibial Nail and the Alta® Advance Tibial/Humeral Rod, they are substantially equivalent in form and function. Both systems are indicated for open, unstable, comminuted, or segmented conditions, gaps resulting from missing bone fragments, bilateral tibial fractures, ipsilateral femoral fractures, fractured associated with compartmental syndrome, and fractures involving vascular injury.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

OCT 3 0 2000

Ms. Angena Parekh
Engineer
Biologically Oriented Protheses
17 Seventeenth Street
Port Huron, Michigan 48060

Re: K002325
Trade Name: WUJIN #3 Tibial Nail
Regulatory Class: II
Product Codes: JDS
Dated: June 6, 2000
Received: August 1, 2000

Dear Ms. Parekh:

We have reviewed your Section 510(k) notification of intent to market the device referenced above and we have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act). You may, therefore, market the device, subject to the general control provisions of the Act. The general control provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (Premarket Approval), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 895. A substantially equivalent determination assumes compliance with the current Good Manufacturing Practice requirement, as set forth in the Quality System Regulation (QS) for Medical Devices: General regulation (21 CFR Part 820) and that, through periodic (QS) inspections, the Food and Drug Administration (FDA) will verify such assumptions. Failure to comply with the GMP regulation may result in regulatory action. In addition, FDA may publish further announcements concerning your device in the Federal Register. Please note: this response to your premarket notification submission does not affect any obligation you might have under sections 531 through 542 of the Act for devices under the Electronic Product Radiation Control provisions, or other Federal laws or regulations.

This letter will allow you to begin marketing your device as described in your 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801 and additionally 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4659. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers Assistance at its toll-free number (800) 638-2041 or at (301) 443-6597, or at its Internet address "http://www.fda.gov/cdrh/dsmamain.html".

Sincerely yours,

for Mark N. Melkerson

Celia M. Witten, Ph.D., M.D.
Director
Division of General, Restorative and
Neurological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

510K) Number (if known): _____

Device Name: Wujin #3 Tibial Nail

Indications For Use:

1) Open, unstable, comminuted, or segmented conditions, gaps resulting from missing bone fragments

2) Bilateral tibial fractures

3) Ipsilateral femoral fractures

4) Fractured associated with compartmental syndrome

5) Fractures involving vascular injury

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

(Division Sign-Off)
Division of General Restorative Devices
510(k) Number K002325

Prescription Use____ OR Over-The Counter Use_____
(Per 21 CFR 801.109)

(Optional Format 1-2-96)